

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 122313-001-SF

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 17th day of October 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On July 12, 2011, XXXXX, authorized representative of his wife XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under Public Act No. 495 of 2006, MCL 550.1951 *et seq.* The Commissioner reviewed the material submitted and accepted the request on July 19, 2011.

The Petitioner receives health care benefits as a retiree of XXXXX, a self-funded plan administered by Blue Cross Blue Shield of Michigan (BCBSM). The Commissioner notified BCBSM of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on July 26, 2011.

Under Section 2(2) of Act 495, MCL 550.1952(2), the Commissioner conducts this external review as though the Petitioner was a covered person under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.*

To analyze the medical issues presented, the Commissioner assigned the case to an independent medical review organization which provided its initial report on August 2, 2011. An additional review was performed at the Commissioner's request to address the specific medical

criteria used by BCBSM to deny the Petitioner's claim. That report was submitted on September 8, 2011, as an addendum to the original report. Copies of both the original report and addendum are provided to the parties with this Order.

II. FACTUAL BACKGROUND

The Petitioner's benefits are contained in BCBSM's *Preferred RX Program Certificate* amended by *Rider RXP (Prescription Drug Preauthorization Requirement)* (the certificate).

The Petitioner is 57 years-old and has degenerative joint disease of the right hip and psoriatic arthritis involving her hands. She has been taking Motrin for the last ten years but has developed gastrointestinal problems. Her physician switched her to Celebrex, a prescription pain medicine for arthritis.

BCBSM denied coverage for this drug ruling that she did not meet its criteria for coverage. The Petitioner appealed the denial through BCBSM's internal grievance process but BCBSM did not change its decision. BCBSM issued a final adverse determination dated June 24, 2011.

III. ISSUE

Did BCBSM properly deny prior authorization for the Petitioner's use of Celebrex?

IV. ANALYSIS

Petitioner's Argument

For more than ten years the Petitioner has taken Motrin and Ultram to control her arthritis. She began to have gastrointestinal problems so her physician switched her to Celebrex. She found with Celebrex her pain and inflammation, as well as her gastrointestinal problems, were relieved. The Petitioner states that BCBSM kept asking for additional information which she and her physician have provided, but that BCBSM eventually denied coverage. She states that her arthritis has become so severe that surgery is now required.

The Petitioner maintains that her physician has determined that Celebrex is medically necessary for the treatment of her condition. She believes it is a covered benefit under her certificate and that BCBSM is required to prior authorize and provide coverage.

BCBSM's Argument

BCBSM argues that the Petitioner's health benefit plan requires preauthorization before coverage is provided for certain prescription drugs, including Celebrex. According to BCBSM, the standards for approving Celebrex require the following:

. . . the patient be over age 60 *or* have concomitant use of anticoagulants or oral steroids *or* risk of gastrointestinal (GI) bleed (history of peptic ulcer disease (PUD), previous GI bleed, alcoholism).

Our Clinical Pharmacy Consultant reviewed the documentation [Petitioner's physician] submitted and determined that the criterion for coverage of Celebrex is not met. Specifically, there is no documentation that you are at least 60 years of age, *or* presently taking anticoagulants (other than aspirin) or presently taking oral steroids or have a risk of gastrointestinal bleeding. Therefore, authorization for the medication Celebrex cannot be approved for you at this time. . . .

Commissioner's Review

The question of whether the Petitioner met BCBSM's criteria for coverage for the drug Celebrex and whether it was medically necessary was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act. The IRO reviewer is a physician in active practice and is certified by the American Board of Internal Medicine with a subspecialty certification in rheumatology. The reviewer is also a member of the American College of Rheumatology and the Arthritis Foundation.

The IRO reviewer's first report includes the following analysis and conclusion:

Numerous studies have shown that COX 2 selective nonsteroidal anti-inflammatory drugs (NSAID) have much better gastrointestinal (GI) tolerability than nonselective NSAID at approved doses. [Citation omitted] This enrollee had no help with Ultram & Motrin and had GI tolerability issues with Motrin, which is a nonselective NSAID. At this point, apart from Celebrex, the enrollee's treatment options include other nonselective NSAIDs such as Diclofenac, Naproxen, and Meloxicam.

The study by Niculescu et al. [Citation omitted] clearly shows that in patients with OA and GI intolerability Celebrex (COX 2 selective NSAID) is much better than Ibuprofen, Diclofenac, and Naproxen (all non nonselective NSAID). Since this enrollee had GI tolerability issues with Motrin the next treatment should be a COX 2 selective NSAID such as Celebrex which has a better GI tolerability profile.

The first line of therapy in management of osteoarthritis includes physical therapy and acetaminophen. [Citation omitted] The enrollee had no relief with Ultram, which has acetaminophen in it. The next line of therapy includes NSAID; she was unable to tolerate the first line NSAID (Motrin); therefore, a selective NSAID should be tried. As discussed above, the best NSAID of choice for this enrollee would be Celebrex.

Although the enrollee had significant alleviation of pain with Celebrex, studies have shown that the efficacy of Celebrex is similar to non selective NSAIDs. . . . In this enrollee's case, Celebrex is medically necessary. . . .

In the September 8 addendum, the IRO made the following comments regarding the test BCBSM applied to determine coverage for Celebrex:

[T]he BCBSM Criteria [are] **not** in line with the current standards of practice within the medical community. If BCBSM Criteria [are] strictly followed, then any patient with osteoarthritis who is under 60 years of age or not on an anticoagulation or oral steroid, or has no prior history of PUD, GI bleed, or alcoholism, and even if they have severe osteoarthritis, would not be eligible to receive Celebrex. This is not in line with current standards of practice.

The Food and Drug Administration (FDA) has approved Celebrex for the treatment of osteoarthritis, without any restrictions. [Citation omitted] Typically, the first line of therapy in the management of osteoarthritis includes physical therapy (PT) and Acetaminophen. The next line of therapy includes nonsteroidal anti-inflammatory [*sic*] drugs (NSAIDs). Physicians typically use Ibuprofen, Naproxen, Diclofenac, and Meloxicam as they are less expensive and generic. If the patient has inadequate response or is unable to tolerate the NSAIDs, it is appropriate to use NSAIDs, such as Celebrex; however, it tends to be more expensive. [Citation omitted] Celebrex also provides better GI protection compared to other NSAIDs (such as Ibuprofen, Naproxen, Diclofenac, and Meloxicam). If the patient has GI intolerance (e.g. heart burn, epigastric pain, etc.) to any of the other NSAIDs, then Celebrex would be used due to its better GI tolerability.

The enrollee has a history of advanced osteoarthritis in her right hip and has been recommended for a right hip replacement. She has not been able to take Motrin as it causes her GI upset/intolerance. She was able to tolerate Celebrex samples without any problems and had significant improvement in her symptoms clinically.

The reviewer recommended that the denial of coverage for Celebrex be overturned.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principle reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

V. ORDER

Blue Cross Blue Shield of Michigan's final adverse determination is reversed. BCBSM is required to provide coverage for the Petitioner's Celebrex prescription. Coverage is to be provided within 60 days of the date of this Order with proof of coverage provided to the Commissioner within seven (7) days of compliance.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free at (877) 999-6442.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, P.O. Box 30220, Lansing, MI 48909-7720.